

March 12, 2001

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Office for Human Research Protections
Office of Public Health and Science, OS
6100 Executive Boulevard, Room 3B01 (MSC7507)
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Re: Comment Letter on OHRP Interim Guidance
"Financial Relationships in Clinical Research Dealing with
Issues of Financial Interest and Human Subjects Protection"

Dear Ms. Gottfried:

Thank you for the opportunity to comment on the Draft Interim Guidance published for comment on January 10, 2001.

This document places new responsibilities on Institutional Review Boards (IRBs), but it is not clear from any supporting documentation that such additional safeguards are needed or desirable. In particular, the document derives from the supposition that IRBs are subjected to institutional pressures that make it difficult for IRB members to freely follow their conscience. Does OHRP have statistical evidence to indicate that chairs or members of IRBs have felt such pressure, either implicit or explicit, in the conduct of their responsibilities? Likewise, with respect to including more unaffiliated members on IRB committees, is there evidence to support that the quality of decision-making will be enhanced by increasing the number of non-affiliated members? How has OHRP arrived at the conclusion that a more reasoned judgment will be arrived at by institutional review through such diversification of composition? It would indeed be unfortunate if such proposed changes were perceived as an indictment that the motives of IRB members, who spend many uncompensated hours of service reviewing protocols and consent forms, are driven by something other than the protection and well-being of human subjects.

Many of the suggestions in the Draft Interim Guidance do not take into account the organizational and management structures of the entities themselves. Universities are large, complex organizations with a multiplicity of management structures. Many university "systems" have multiple and physically separate campuses with varying degrees of autonomy in institutional governance. Some are decentralized by school or college in their approach to management. Often, universities are the largest single employers in their area. When such factors are weighed against certain recommendations
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in the Draft Guidance, an individual clinical investigator would not likely be in a position to know if the proposed sponsor of a clinical trial had other "business arrangements" with the university. In such a situation, it is unlikely he/she would be affected by such an arrangement. The institution could receive charitable donations from a company that is also a sponsor of clinical research, but there is not necessarily a link between the philanthropic activity and the clinical research.

It is unclear what standard will meet the diligence requirements expected by OHRP. Would an investigator (or the IRB) be required to run a query of any philanthropy, and for what period of time? Would it be necessary to search for alumni records to identify institutional graduates employed by a particular company prior to entering into a contract? Would the relative position of an alumnus within a company need to be considered before a contract is signed? The actual implications of this suggestion, if taken through exhaustive measures, could create administrative gridlock without adding additional protections for human subjects. It could also place the IRB in a role of investigative reporting.

At Tulane, as at our sister institutions, the role of the IRB is to protect the welfare and well being of human subjects. It is that objective that we focus on and refine. In speaking to colleagues across the country, most institutions are actively engaged in self-assessment and/or self-correction. Such internal analysis has escalated since Secretary Shalala's initiatives were announced in May of 2000. The institutions and the IRBs take seriously the obligations imposed on them. This latest Draft Interim Guidance seems to emanate from a belief that financial and/or business pressures are driving decision-making, but the basis for this assumption is never made clear. I would favor additional and continued dialogue on this matter, including another conference convened by OHRP. That would allow institutions to report to OHRP on changes that have emanated in the past year.

Thank you for your consideration on these points.

Yours sincerely,

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